Welcome to

FDA/CDRH Training Module

U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

C·D·R·H

Center for Devices and Radiological Health

GUDID Global Unique Device Identification Database

HL7 SPL Submission Option Overview

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Agenda

- GUDID HL7 SPL Submission Process
- FDA Electronic Submissions Gateway
- Submission Acknowledgements
- GUDID HL7 SPL Submission Testing
- Using Third Party Submitters
- HL7 SPL submission Pointers
- Editing HL7 SPL submissions
- How to Contact Us

Unique Device Identification System

- 2007 FDAAA – the system
- 2012 FDASIA – the timelines
- 2012 Proposal – 77 FR 40736
- 2013 Final Rule– 78 FR 58786

CDRH Learn – www.fda.gov/CDRHLearn –- look under **Unique Device Identification (UDI) System** for previous training webinars on:

- The UDI Final Rule
- GUDID Overview
- GUDID Accounts
- GUDID DI Record

Compliance Date	Must bear a UDI & submit data to GUDID
September 24, 2014	• Class III devices, incl. class III stand alone software • Devices licensed under the PHS Act
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software • Direct Marking of I/LS/LS for certain intended uses
September 24, 2016	• Class II devices • Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses
September 24, 2018	• Class I devices and devices not classified class I, II or III • Direct Marking of class II devices for certain intended uses
September 24, 2020	• Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses

UDI = Unique Device Identifier

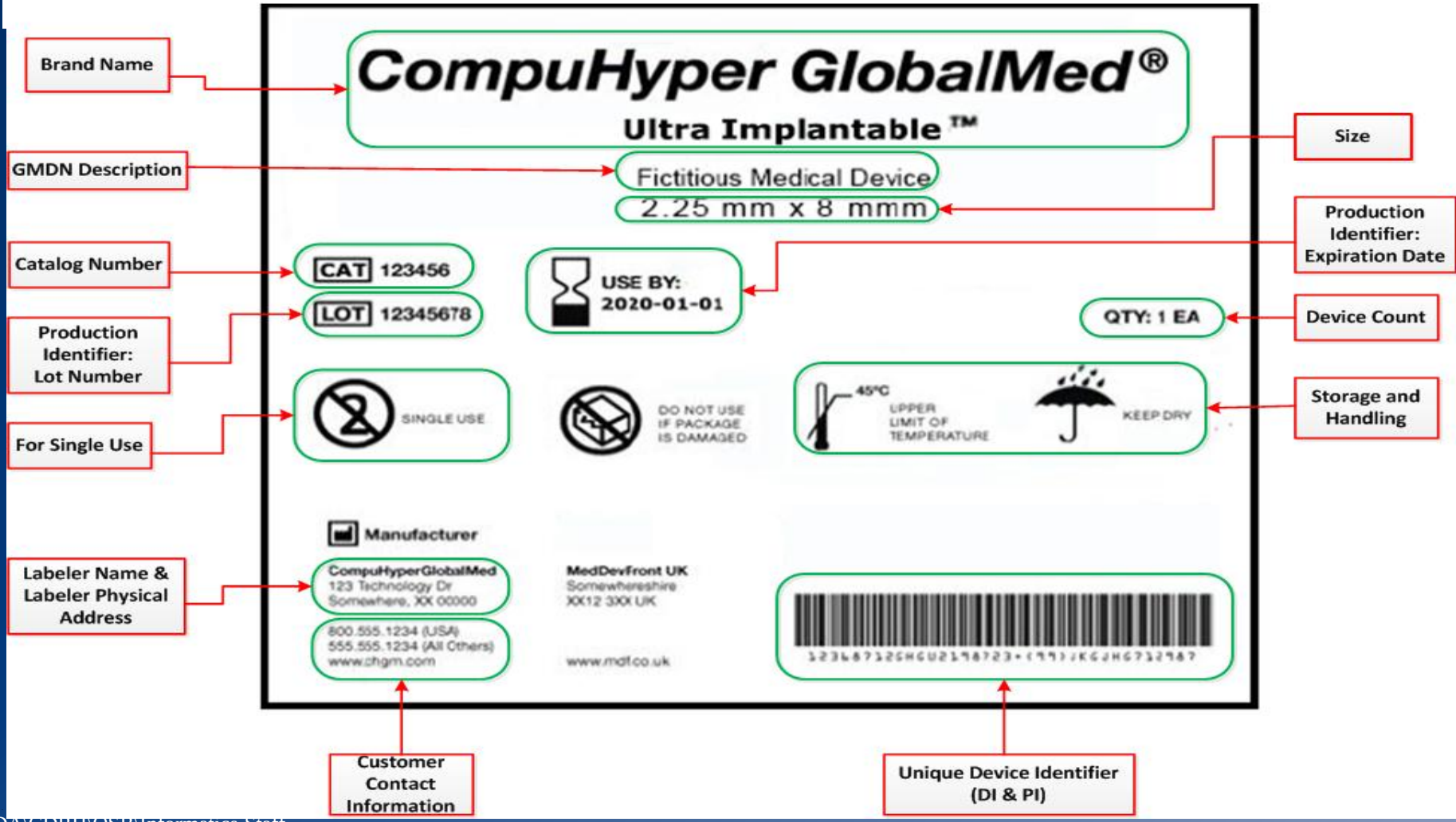
- Device Identifier(DI) + Production Identifier(s)(PI)
- DI= mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device
- PI= a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
  - Lot or batch number
  - Serial number
  - Expiration date
  - Manufacturing date
  - For an HCT/P regulated as a device, the distinct identification code

GUDID Global Unique Device Identification Database

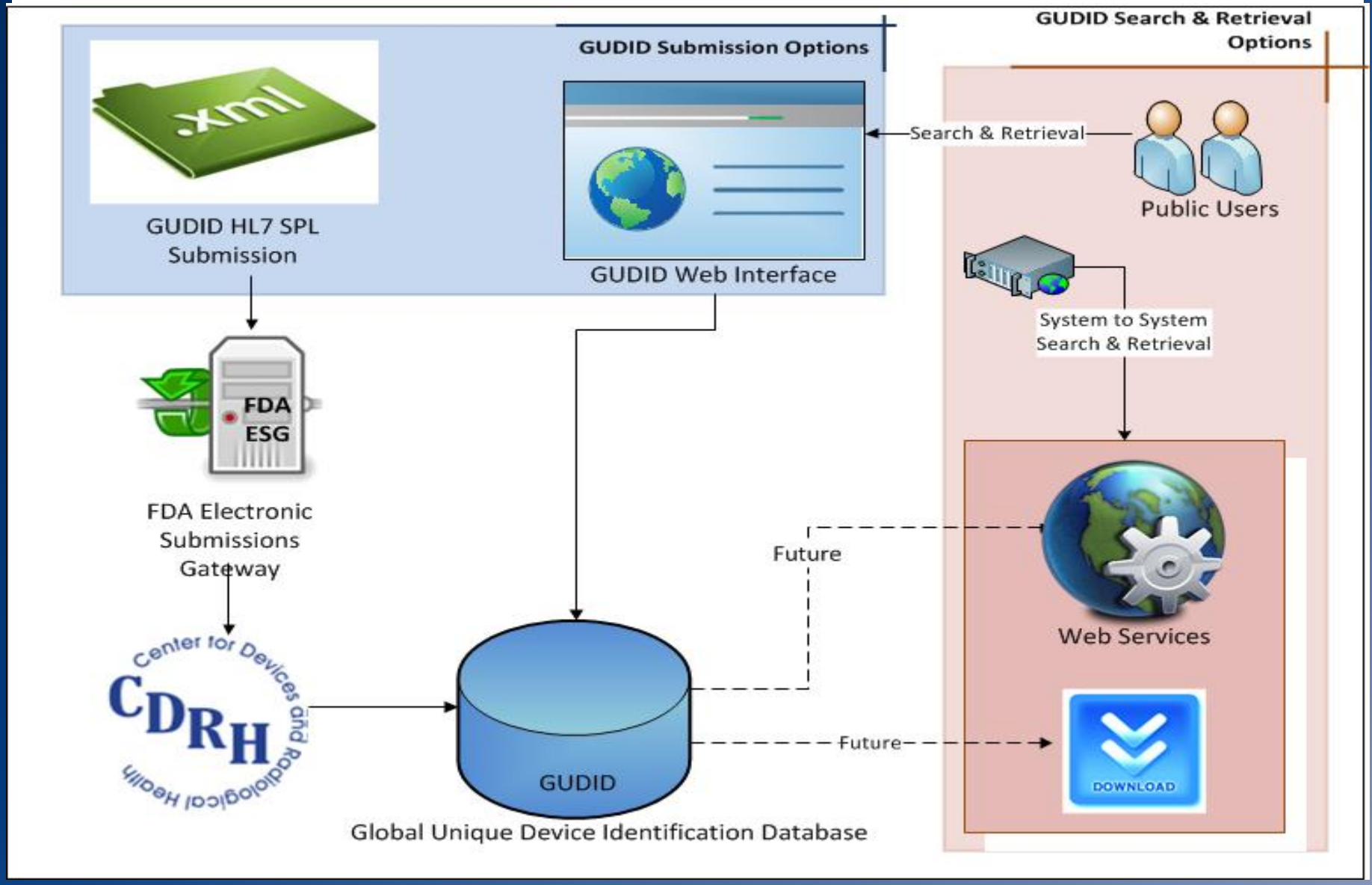
- Repository of key device identification information
- Contains ONLY the DI; PIs are not submitted to or stored in the GUDID
  - Contains only PI flags to indicate which PI attribute(s) are on the device label

DI Record

DI Record = Device Identifier (DI) + GUDID attributes

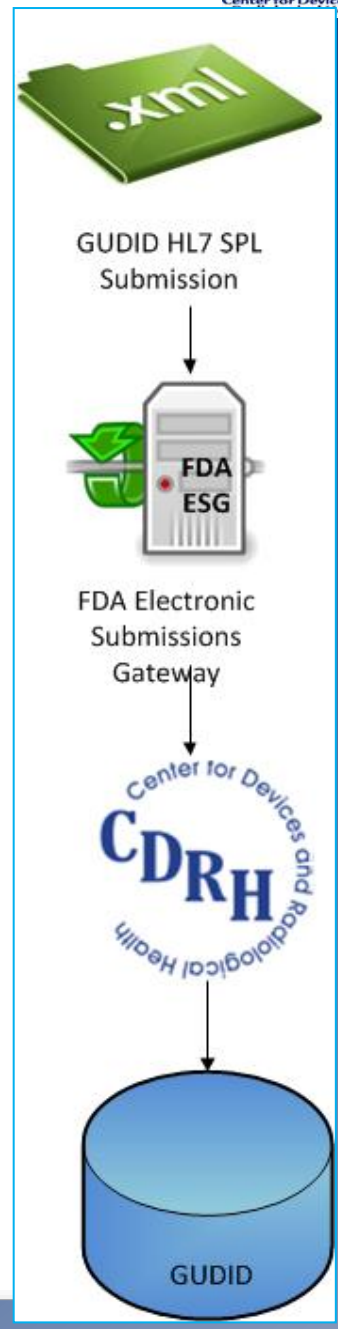


GUDID Overview



GUDID HL7 SPL Submission Option

- HL7 = Health Level 7
- SPL = Structured Product Labeling
- Submission of device information as xml files, one DI record at a time
- Technical specifications available on the UDI website
- Submissions sent via the FDA Electronic Submissions Gateway (ESG)
- Testing required prior to production submission



HL7 SPL Submission – Process

- Register with the FDA ESG
- Complete ESG testing
- Request a test GUDID Account
- Complete GUDID HL7 SPL testing
- Request and obtain a production GUDID Account
- Submit DI records

FDA ESG

- Enables secure receipt of regulatory submissions
- Routes submissions to the appropriate Center
- Two options for submission
  - WebTrader (Low Volume)
  - B2B (High Volume)
- Acknowledgements for each stage of report transmission
- www.fda.gov/esg

FDA Electronic Submissions Gateway

Acknowledgements

Original slide courtesy of Eugene Reilly, FDA\CDRH

Acknowledgements

Ack1/Receipt/MDN

```
This MDN (Message Disposition Notification) was automatically built on
Tue, 25 Mar 2014 23:36:26 GMT in response to a
message with id <20425118.41395790583689 JavaMail.John.ADAMS@ABC1234567> received from
ZZFDAIST on Tue, 25 Mar 2014 23:36:25 GMT.
Unless stated otherwise, the message to which this MDN applies
was successfully processed.
```

Ack2

```
MessageId:<20425118.41395790583689 JavaMail.John.ADAMS@ABC1234567>
CoreId: ci1395790584826.2538@fdsul05622_te2
DateTime Receipt Generated: 03-25-2014, 19:36:52
File Count: 1Directory Count: 2

CDRH has received your submission
```

Ack3

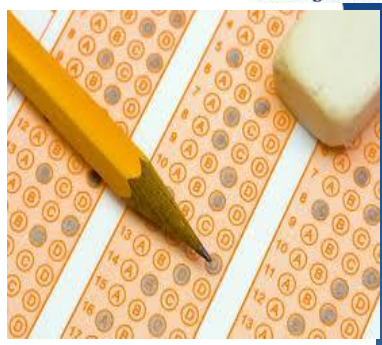
```
- <submission>
    <coreId>ci1395790584826.2538@fdsul05622_te2</coreId>
    <batchId>2</batchId>
    <dateEntered>03-25-2014, 19:36:52</dateEntered>
    <numReportFailed>0</numReportFailed>
    <numReportPassed>1</numReportPassed>
  - <report id="11111111100010">
      <status>passed</status>
    </report>
  </submission>
```

```
<html><body><p>Unidentified or unparseable submission type [CoreID]</p></body></html>
```

FDA ESG and GUDID

- Request a test ESG account
  - Obtain a digital certificate
  - Send a letter of non- repudiation
- Complete ESG testing
  - Connectivity test
  - Load test
- Existing test accounts can be used
- Be sure to specify- -
  - Center = CDRH
  - Submission Type = GUDID

GUDID HL7 SPL Testing



- Generate your DI records as xml files
- Request a test GUDID account
  - same account request process – indicate you need a test account
- Do thorough testing via your ESG test account
- Complete the required test scenarios
- Request to move to production submissions via the FDA UDI Help Desk
  - Send Primary DI and coreID with your request
- FDA Staff will review your submission and give you the green- light for production submissions

Using Third-Party Submitters

- Third- parties may- -
  - Provide software solution/tool to the labeler to generate HL7 SPL xml files; labeler sends submission via ESG
    - Labeler obtains the test ESG account
  - Provide end- to- end solution – generate GUDID data as HL7 SPL xml files AND send submissions via the ESG on behalf of labeler
    - Third- party has the ESG test account
    - Labeler sends a letter of non- repudiation indicating third- party is authorized to submit on their behalf
- Provide third- party information during GUDID account request

Using Third-Party Submitters

- We are enabling third- parties to test HL7 SPL solutions
- If you use a third- party who has completed testing their solution, must still test with your data
- Labeler is responsible for fulfilling GUDID submission requirements–
  - ensuring submissions are received and processed by the FDA.
  - reporting within the required timeframe
  - record keeping

If you are a Third-Party Solution Provider…

- May test your GUDID HL7 SPL submission solution independently of Labelers
  - Request a GUDID test Account - indicate it is for HL7 SPL testing
  - Dummy data for certain required attributes will be provided for testing purposes ONLY, upon request
  - GUDID Production accounts NOT provided

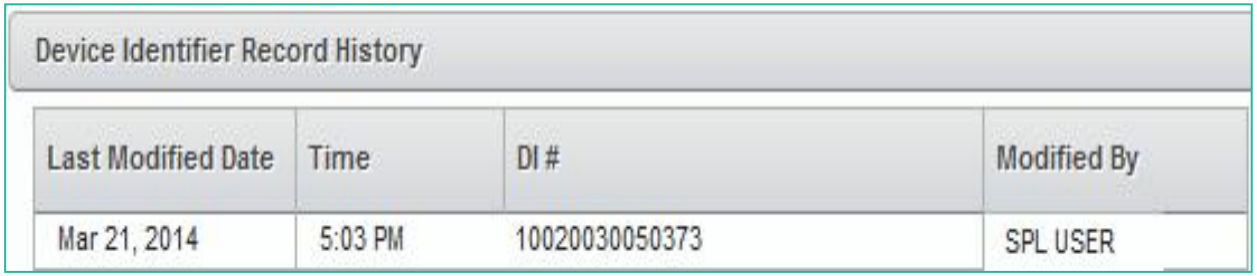
- As you work with labelers, must complete GUDID HL7 SPL testing with each labeler

GUDID HL7 SPL Pointers

- Important to read “GUDID Guidance for Industry and FDA Staff” document
- Allow adequate time for ESG set- up and testing
- When submitting via ESG, please specify Center = *CDRH*, Submission Type = *GUDID*
- GUDID testing completion criteria is the bare minimum
  - Please do thorough internal testing to ensure the scenarios appropriate for your products are accounted for
- Do not submit sample message in the HL7 SPL implementation package as a test submission – it is not validated

GUDID HL7 SPL Pointers

- Draft DI record state is not available
- Records can be submitted as –
  - Unpublished – DI Record Publish Date > today
  - Published – DI Record Publish Date <= today
- Can review your submission via the Web Interface
  - Login as a Labeler Data Entry (LDE) user
  - Labeler DUNS number for that DI record should be assigned to you


Device Identifier Record History

Last Modified Date	Time	DI #	Modified By
Mar 21, 2014	5:03 PM	10020030050373	SPL USER

GUDID HL7 SPL Pointers

- Submission Folder Structure must be followed
  - Top level folder must be uniquely named
  - Lower level folder must always be named “spl”
  - The GUDID HL7 SPL xml submission file must be named “submission.xml”
  - Do not include any other files in the “spl” folder
- Only one submission (one DI record) in each folder structure

Editing HL7 SPL Submissions

- Submit the entire DI record, i.e., include changed and unchanged attributes
  - docment.setID – links submission edits to the prior submissions
  - document.versionNumber – increment by 1; the highest number will be considered the most recent
  - DI record will be over- written with the most recent file

Editing DI records

- Use the same submission option used for initial DI record entry for all edits to the DI record
- Unpublished DI Record
  - Initial entry via Web Interface → CANNOT edit via HL7 SPL Option
  - Initial entry via HL7 SPL → may edit via Web Interface
- Published DI Record
  - During grace period
    - Initial entry via Web Interface → CANNOT edit via HL7 SPL Option
    - Initial entry via HL7 SPL → may edit via Web Interface
  - After grace period
    - Initial entry via Web Interface → CANNOT edit via HL7 SPL
      - Planned enhancement to allow this capability
    - Initial entry via HL7 SPL → may edit via Web Interface

Edits to New DI Trigger attribute After Grace Period

- Expected to be an extremely rare occurrence
  - BEFORE publishing a DI record, make sure your data is accurate and "ready" to be *Published*
- However, if necessary to edit AFTER grace period–
  - Contact FDA UDI Help Desk with your request
  - FDA Staff will review your request and change the DI record to "Unpublished" state
  - You can make your edits and then Publish the record

DI Record Submission

- Start by submitting your records as “unpublished” DI records
- Work with us on data quality review
- Make edits as necessary
- Publish your DI records

GUDID System Status

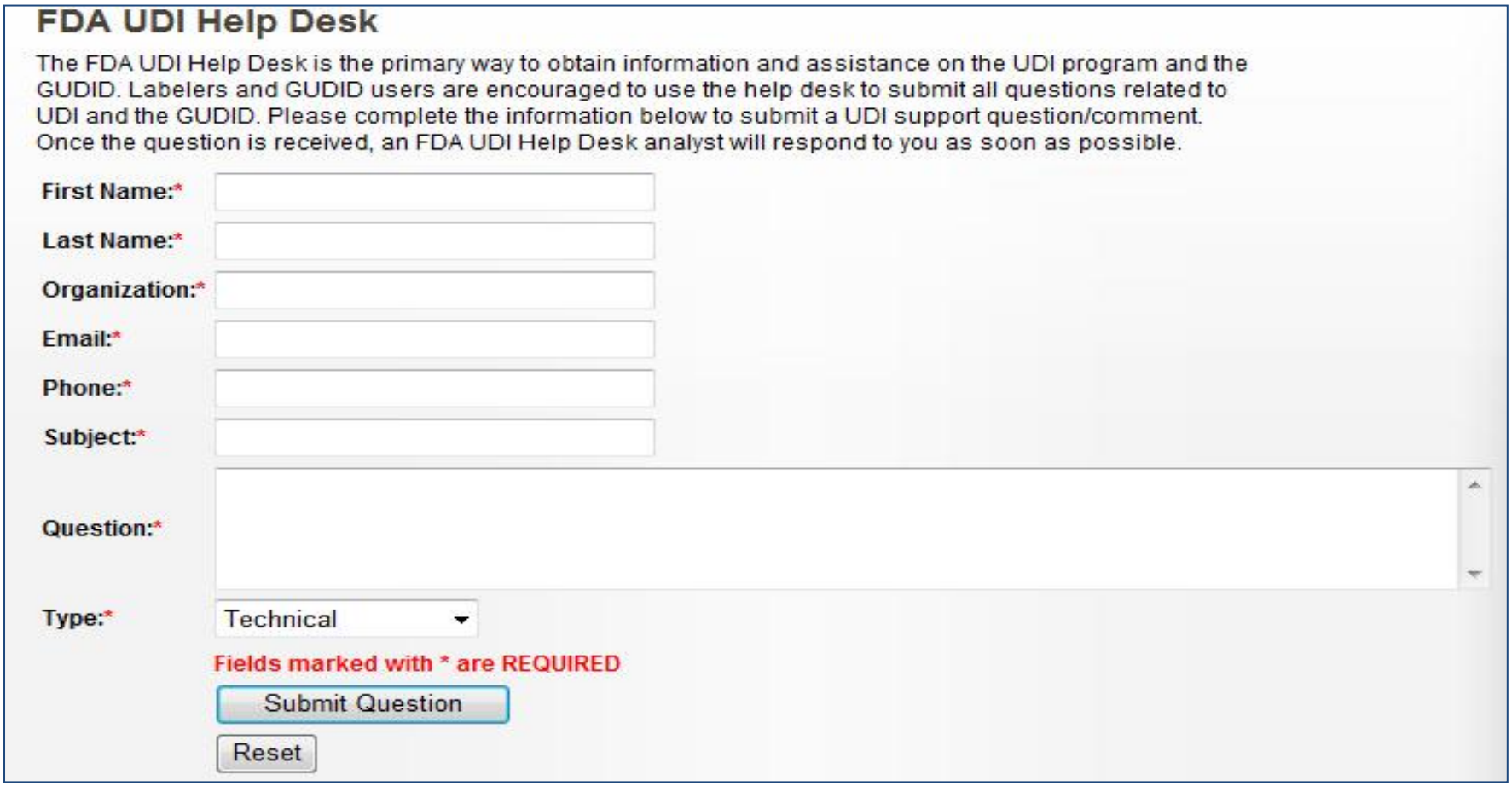
- Scheduled downtimes will be posted on www.fda.gov/udi, look for GUDID System Status
- Unscheduled downtimes
  - Visit www.fda.gov/udi for information
  - If no information, report issue via Help Desk
- Subscribe to GUDID Email Alerts 

How to Contact Us

- Contact FDA ESG, esghelpdesk@fda.hhs.gov
  - FDA ESG questions, account set up
  - Ack1/Ack2 issues
- Contact FDA UDI Help Desk
  - HL7 SPL submission option process, questions
  - Ack3 issues
  - GUDID Account Request – production and test
  - Regulatory questions
  - Technical questions

FDA UDI Help Desk

- Submit question via the web, www.fda.gov/udi
- Please complete all fields on the web form!



FDA UDI Help Desk

- Question becomes a “case” in help desk tool
- Response will be sent to the email you provide
  - Ask follow-up questions by responding to the email, will append the “case”
- Please ensure you can receive emails from help desk – check your spam folder

Questions?

For questions on all things UDI/GUDID:
FDA UDI Help Desk, www.fda.gov/udi

For Questions on FDA ESG:
esghelpdesk@fda.hhs.gov

Division of Industry and Consumer Education: DICE@fda.hhs.gov

CDRHQuestions@fda.hhs.gov